APR 3 0 2004

k031687
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510(k) Summary of Safety & Effectiveness

Submitter	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
Contact	Heather Crawford, RAC Director of Regulatory Affairs (863) 683-8680, extension 249 (863) 683-8703 (facsimile) hcrawford@safe-reuse.com
Date	May 30, 2003
Device	• Trade Names: Vanguard Reprocessed External Fixation Devices ⇒ Stryker® Trauma External Fixation Devices ⇒ Synthes® (USA) External Fixation Devices • Common Name: External fixation devices • Classification: 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories – Class II • Product Code KTT
Predicate Devices	Respective Stryker® Trauma and Synthes® legally marketed external fixation devices under various 510(k) premarket notifications.
Indications for Use	External fixation components are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.
Contra-indications	• External fixation systems are contraindicated in patients with mental or neurologic impairment that would interfere with cooperative postoperative care. • These devices are not intended for attachment or fixation of screws to the spine.

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510(k) Summary of Safety & Effectiveness, Continued

Device Description

External skeletal fixator systems are comprised of various elements that, when used in conjunction with one another, form bridge constructs to which anchoring screws, wires and/or pins, may be attached. Bridge elements are designed to provide a framework for stabilization of bone fractures where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, or other means of internal fixation. External fixator elements consist of components such as straight and curved rods, tubes, rod-to-rod, and rod-to-pin couplings and clamps, rings and ring segments, ring-to-rod, and ring-to-pin clamps.

Rods and Tubes ~ Straight rods and tubes are unilateral external fixation devices of varying lengths and diameters that are used with rod-to rod and pin-to-rod clamps by the surgeon to connect anchoring pins, screws and wires together to form a rigid structure that immobilizes the affected bone or structures. Differences in length and diameter of the rods or tubes allow accommodation of a broad range of fracture scenarios and applied loads. All rods have a straight, solid, round design. Tubes are normally larger diameter than rods, and are therefore typically lighter than a solid rod of the same material and diameter, while retaining similar load bearing capabilities to a solid rod of equal diameter. Rods and tubes are typically constructed of either stainless steel, carbon fiber, or aluminum.

Curved rods are multilateral devices bent in shapes useful for some constructs where straight rods are less suitable. These rods allow the surgeon to connect pins in various locations in the limb together to form a rigid structure. Curved rods are manufactured from either aluminum or stainless steel.

Rod-to-Rod Couplings or Clamps ~ These are multi-element components used to connect one rod or tube to another in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rods or tubes. The devices are typically constructed from one or more of the following materials: anodized aluminum alloys, steel or stainless steel alloys and titanium alloys.

Rod or Tube-to-Pin Couplings or Clamps ~ These are multi-element components used to connect one rod or tube to a pin or group of pins in a range of positions defined by the individual clamp configuration. They are designed to interconnect a specific size or range of sizes of rods or tubes to

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Device Description, continued

specific sizes or ranges of sizes of pins. The devices are typically constructed from one or more of the following materials: Anodized aluminum alloys, steel and/or stainless steel alloys and titanium alloys.

Rings and Ring Segments ~ These are circular or semicircular segments manufactured to surround the area of attachment to bone located centrally in the ring. Various attachments are made to the rings or ring segments to stabilize bone fractures or to reduce or extend the length of bones. Tensioned wires or pins are commonly attached to rings and ring segments using clamps designed for this purpose. Multiple ring or ring segment constructs are used to stabilize and structurally support the anatomical structures being treated using a range of configurations and attachments and connectors. The rings and ring segments are manufactured in a range of diameters to allow selection of a size most appropriate to the anatomy and application needed. Rings and ring segments are typically manufactured from one or more of the following materials: anodized aluminum alloys, steel and stainless steel alloys or carbon fiber composites.

Ring-to-Rod Clamps ~ Ring-to-rod clamps are utilized to connect a ring or ring segment to a rod. These attachments are made to form an external fixator frame construct as required for the particular biomechanical needs of the procedure. Ring to rod clamps are typically constructed from one or more of the following materials: anodized aluminum alloys, steel and/or stainless steel alloys and titanium alloys.

Ring-to-Pin or Ring-to-Wire Clamps ~ Ring-to-pin or wire clamps are utilized to connect an external fixation ring or ring segment to a pin or wire that is normally affixed to the bone passing centrally through the ring. Wires are normally attached on one side of the ring, passed through the bone, and continue to an attachment point on the opposite side of the ring where they are affixed under tension to another ring to wire clamp. Ring-to-pin clamps are used to secure the ring to a pin or set of pins that are anchored in the bone passing centrally through the external fixation ring. Ring-to-pin and ring-to-wire clamps are typically constructed from one or more of the following materials: anodized aluminum alloys, steel and/or stainless steel alloys and titanium alloys.

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510(k) Summary of Safety & Effectiveness, Continued

Device Description, continued	Vanguard receives previously used external fixation devices from healthcare facilities. These devices are cleaned, inspected, tested, repackaged and returned to the healthcare facility.
Technological Characteristics	The Vanguard reprocessed external fixation devices are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Performance/functional testing demonstrates the devices are equivalent and continue to be safe and effective for their intended use.
Test Data	Performance, sterilization and packaging validations demonstrate that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed external fixation devices are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2004

Ms. Heather Crawford, RAC
Director of Regulatory Affairs
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K031687
Trade/Device Name: Vanguard Reprocessed External Fixation Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: January 30, 2004
Received: February 2, 2004

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

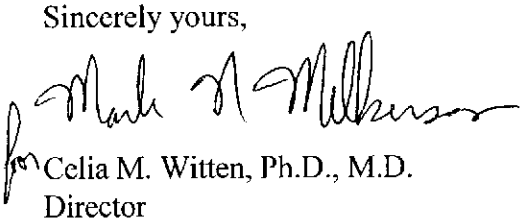
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K031687

Device Name: Vanguard Reprocessed External Fixation Devices

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson IV

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031687

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